

## PART 178—OBJECTIONS AND REQUESTS FOR HEARINGS

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AUTHORITY: 21 U.S.C. 346a, 348, 371(a); Reorg. Plan No. 3 of 1970.

SOURCE: 55 FR 50291, Dec. 5, 1990, unless otherwise noted.

### Subpart A—General Provisions

#### § 178.3 Definitions.

For the purposes of this part:

*Administrator* means the Administrator of the Agency, or any officer or employee of the Agency to whom the Administrator delegates the authority to perform functions under this part.

*Agency* means the United States Environmental Protection Agency.

*Assistant Administrator* means the Agency's Assistant Administrator for Prevention, Pesticides and Toxic Substances, or any officer or employee of the Agency's Office of Prevention, Pesticides and Toxic Substances to whom the Assistant Administrator delegates the authority to perform functions under this part.

*FFDCA* means the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. 301–392.

[55 FR 50291, Dec. 5, 1990, as amended at 57 FR 28087, June 24, 1992]

## Subpart B—Procedures for Filing Objections and Requests for Hearing

### § 178.20 Right to submit objections and requests for a hearing.

(a) On or before the 30th day after the date of publication in the FEDERAL REGISTER of an order under part 177 or part 180 of this chapter establishing, modifying, or revoking a regulation, or an order under part 177 of this chapter denying all or any portion of a petition, a person adversely affected by such order or petition denial may submit, in accordance with § 178.25, one or more written objections to the order (or to the action that is the subject of the order).

(b) A person may include with any such objection a written request for an evidentiary hearing on such objection in accordance with § 178.27.

(c) A person who submits objections need not request a hearing. For instance, if the person's objections are of a purely legal or policy nature, a hearing request would be inappropriate; the purpose of an evidentiary hearing is to resolve factual disputes. The Administrator will rule on the objections, whether or not a hearing is requested.

(d) As a matter of discretion, the Administrator may order a hearing on an objection even though no person has requested a hearing.

### § 178.25 Form and manner of submission of objections.

(a) To be considered by the Administrator, an objection must:

(1) Be in writing.

(2) Specify with particularity the provision(s) of the order, regulation, or denial objected to, the basis for the objection(s), and the relief sought.

(3) Be signed by the objector.

(4) State the objector's name and mailing address.

(5) Be accompanied by the fee prescribed by § 180.33(i) of this chapter, if the objection is to an order or regulation issued under part 180 of this chapter.

(6) Be submitted to the hearing clerk.

(7) Be received by the hearing clerk not later than the close of business of the 30th day following the date of the publication in the FEDERAL REGISTER

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of the order to which the objection is taken (or, if such 30th day is a Saturday, Sunday, or Federal holiday, not later than the close of business of the next government business day after such 30th day).

(b) Submissions to the hearing clerk shall be made as follows:

(1) Mailed submissions should be addressed to: Office of the Hearing Clerk (A-110), U.S. Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

(2) For personal delivery, the Office of the Hearing Clerk is located at: room M3708, Waterside Mall, 401 M St., SW., Washington, DC.

### **§ 178.27 Form and manner of submission of request for evidentiary hearing.**

To be considered by the Administrator, a request for an evidentiary hearing must meet the criteria in § 178.32, and must:

(a) Be submitted as a part of, and specifically request an evidentiary hearing on an objection that complies with the requirements of § 178.25.

(b) Include a statement of the factual issue(s) on which a hearing is requested and the requestor's contentions on each such issue.

(c) Include a copy of any report, article, survey, or other written document (or the pertinent pages thereof) upon which the objector relies to justify an evidentiary hearing, unless the document is an EPA document that is routinely available to any member of the public.

(d) Include a summary of any evidence not described in paragraph (a)(3) of this section upon which the objector relies to justify an evidentiary hearing.

(e) Include a discussion of the relationship between the factual issues and the relief requested by the objection.

### **§ 178.30 Response by Administrator to objections and to requests for hearing.**

The Administrator will respond to objections, and to requests for a hearing on such objections, as set forth in this section.

(a) *Denial of objections that are improperly submitted or that seek an unavailable form of relief.* The Administrator will by order issued under § 178.37 deny each

objection and each request for a hearing that is included with such an objection, if:

(1) The objection is found not to conform to § 178.25.

(2) The action requested by the objection is inconsistent with any provision of FFDCA.

(3) The action requested by the objection is inconsistent with any generic, e.g., non-chemical specific, interpretation of a provision of FFDCA in any regulation in this chapter (the proper procedure in such a case is for the person to petition for an amendment of the regulation involved).

(b) *Denial of improperly submitted requests for hearing.* The Administrator will then determine whether any objection that has not been denied under paragraph (a) of this section was accompanied by a request for an evidentiary hearing that conforms to § 178.27. The Administrator will deny under § 178.37 each request that does not conform to § 178.27.

(c) *Grouping of certain related objections.* If the Administrator then finds (1) That two or more undenied objections are substantially similar, or are related in such a way that any judicial review of the Administrator's action on those objections should occur at the same time, and (2) that one or more of those objections was accompanied by an undenied request for an evidentiary hearing on that objection, the Administrator will treat those objections as a group and will rule on them only after ruling under § 178.32 on the associated request for hearing.

(d) *Rulings on objections for which a request for hearing has been granted.* If the Administrator rules under § 178.32 that an evidentiary hearing should be held on an objection, the Administrator will resolve the issues raised by any other objection grouped with it under paragraph (c) of this section in conjunction with the evidentiary hearing upon which the hearing request was granted, unless the Administrator for good cause determines otherwise.

(e) *Rulings on objections for which no request for hearing was received, or for which each request for hearing was denied.* Except as provided in paragraphs (c) and (d) of this section, if no hearing was requested on an objection, or if